5. A composition comprising activated autologous lymphocytes effective against viral infections, said activated autologous lymphocytes being derived from a culture medium comprising autologous lymphocytes, anti-CD3 antibodies in a solid phase and interleukin-2.

6. The composition according to claim 5, wherein the autologous lymphocytes in the culture medium are derived from an immunodeficient or immunosuppressed patient.

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7. The composition according to claim 5, wherein the autologous lymphocytes in the culture medium are derived from a virally infected patient.

8. A method of preparing the composition according to claim 5, comprising culturing autologous lymphocytes, anti-CD3 antibodies in a solid phase and interleukin-2 in a culture medium to proliferate, stimulate and activate the autologous lymphocytes.

9. A method for treating viral infections comprising administering to a patient the composition according to claim 5.

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

The specification has been carefully reviewed and editorial changes have been effected. All of the changes are minor in nature and therefore do not require extensive discussion. In particular, the specification headings have been amended in conformance with U. S. practice.

Claims 1-4 have been cancelled and rewritten as new claims 5-9. The new claims are presented to put the claims in better form under U. S. practice and to overcome the Examiner's rejections under 35 USC § 112, first and second paragraphs. Support for the new claims is readily apparent from the teachings of the specification and the original claims.

With regard to the rejections of claims 1-4 under 35 USC § 112, first and second paragraphs, these rejections have been overcome in view of the wording of the new claims. Specifically, the claims have been rewritten to exclude the terms "preventatives or prevention" and "remedies". The new claims are now directed to a composition, a method of making thereof, and a method of treating viral infections. Thus, in view of the new claims, Applicants respectfully request that the rejections of claims 1-4 under 35 USC § 112, first and second paragraphs, be withdrawn.

With regard to the rejection of 1-4 under 35 USC § 103(a) as being unpatentable over Ochoa et al. in view of Rosenberg, this rejection is deemed to be untenable and is thus respectfully traversed.

To establish a *prima facie* case of obviousness, the cited references must provide a basis for modifying the teachings of the prior art. Further, one skilled in the art must also reasonably expect that the modification would be successful based upon the teachings and suggestions of the prior art. Here, Ochoa et al. show only a preparation of lymphocytes against tumors and does not

at all teach or suggest activated autologous lymphocytes exhibiting antiviral activity. The cited reference only discusses generally the preparation of lymphocytes using anti-CD3 antibody and IL-2 which have already been reviewed in the Background section of the specification. In other words, the teachings provided by Ochoa et al. is substantially identical with JP03-80076A noted in the specification.

Likewise, the reference of Rosenberg is related to lymphocytes prepared using IL-2 only which is fundamentally distinct from the present lymphocytes using anti-CD3 in addition to IL-2. The Rosenberg reference merely shows the generalities of IL-2 applicable for medical treatment of immune dysfunctional diseases but does not prove whether the lymphocytes prepared using only IL-2 are effective on viral infections or not. It is important to note that the cited reference Rosenberg only mentions viral infections in passing (see column 4, lines 49-54), and does not contain any data or teachings which prove and enable one skilled in the art to make and use activated autologous lymphocytes against viral infections. In fact, the reference, Nature Medicine, 1(4) pp. 330-336 (1996), discloses that lymphocytes prepared using IL-2 were not effective in remedying HIV infections, as stated on page 4 of the specification. Thus, there is clearly no teaching or suggestion in the cited references that activated autologous lymphocytes as recited in the present invention would be effective against viral infections. As a result, the teachings and suggestions of both of these references does not create a reasonable expectation of success to one skilled in the art that activated autologous lymphocytes being derived from a culture medium comprising autologous lymphocytes, anti-CD3 antibodies in a solid phase and interleukin-2 would be very effective for viral infections.

Therefore, since a *prima facie* case of obviousness cannot be established, this rejection under 35 USC § 103 cannot be sustained and should be withdrawn.

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is now in condition for allowance. Such action is thus respectfully solicited.

If, however, the Examiner has any suggestions for expediting allowance of the application or believes that direct contact with the Applicant's attorney will advance the prosecution of this case, the Examiner is invited to contact the undersigned at the telephone number below

Respectfully submitted,

Teruaki SEKINE et al.

By: _____

Lee Cheng
Registration No. 40,989
Attorney for Applicants

LC/gtn
Washington, D.C.
Telephone (202) 721-8200
Facsimile (202) 721-8250
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